4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0090]

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval." This guidance clarifies FDA's current policy on balancing premarket and postmarket data collection during the Agency's review of premarket approval applications (PMA). Specifically, this guidance outlines how FDA considers the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of safety and effectiveness. FDA believes this guidance will improve patient access to safe and effective medical devices that are important to public health by improving the predictability, consistency, transparency, and efficiency of the premarket process.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993-0002, 301-796-5178; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long applied postmarket controls as a way to reduce premarket data collection, where appropriate, while assuring that the statutory standard for approval of reasonable

assurance of safety and effectiveness is still met. The right balance of premarket and postmarket data collection facilitates timely patient access to important new technology without undermining patient safety.

In this guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the policy on balancing premarket and postmarket data collection during review of PMAs. In addition, FDA clarifies how the Agency considers postmarket data as part of the benefit-risk framework described in FDA's guidance "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications," issued on March 28, 2012. This guidance provides a resource for industry and FDA staff on how FDA determines when it is appropriate for a sponsor of a PMA to collect some data (clinical or non-clinical) in the postmarket setting, rather than premarket.

A draft of this guidance was made available in the Federal Register on April 23, 2014, and the comment period closed July 22, 2014. Changes between the draft and final versions of this guidance include an increased focus on patient outcomes and additional examples to help industry better understand when it may be appropriate to shift data collection from the premarket to postmarket setting. The final guidance also recognizes the potential for use of registry data to satisfy post-approval study requirements.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on balancing premarket and postmarket data collection for devices subject to premarket approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Persons unable to download an electronic copy of "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1833 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449; the collection of information in 21 CFR part 860, subpart C have been approved under OMB control number 0910-0138; and the

collections of information in the guidance document regarding requests for feedback on medical device submission have been approved under OMB control number 0910-0756.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-08363 Filed: 4/10/2015 08:45 am; Publication Date: 4/13/2015]